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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/061,043	01/30/2002	David J. Glass	REG753B	8223

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EXAMINER	
KERR, KATHLEEN M	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 01/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/061,043	GLASS ET AL.	
	Examiner	Art Unit	
	Kathleen M Kerr	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 March 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-32* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Application Status

1. Claims 1-32 are pending in the instant application.

Restriction

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-3 and 5-8, drawn to nucleic acids and related products encoding a rat MAFBX protein (SEQ ID NO: 24), classified in class 536, subclass 23.5.

II. Claims 1-3 and 5-8, drawn to nucleic acids and related products encoding a human MAFBX protein, clone K8 (SEQ ID NO: 26), classified in class 536, subclass 23.5.

III. Claims 1-3 and 5-8, drawn to nucleic acids and related products encoding a human MAFBX protein, clone D18 (SEQ ID NO: 34), classified in class 536, subclass 23.5.

IV. Claim 4, drawn to a MAFBX rat protein (SEQ ID NO:25), classified in class 530, subclass 350.

V. Claim 4, drawn to a MAFBX human protein, clone K8 (SEQ ID NO:27), classified in class 530, subclass 350.

VI. Claim 4, drawn to a MAFBX human protein, clone D18 (SEQ ID NO:35), classified in class 530, subclass 350.

VII. Claims 9-10, drawn to a transgenic animal with an extra or inactivated MAFBX rat gene (SEQ ID NO:24), classified in class 800, subclass 8.

VIII. Claims 9-10, drawn to a transgenic animal with an extra or inactivated MAFBX human gene, clone K8 (SEQ ID NO:26), classified in class 800, subclass 8.

IX. Claims 9-10, drawn to a transgenic animal with an extra or inactivated MAFBX human gene, clone D18 (SEQ ID NO:34), classified in class 800, subclass 8.

X. Claim 11, drawn to an antibody to MAFBX rat protein (SEQ ID NO:25), classified in class 530, subclass 387.1.

XI. Claim 11, drawn to an antibody to MAFBX human protein, clone K8 (SEQ ID NO:27), classified in class 530, subclass 387.1.

XII. Claim 11, drawn to an antibody to MAFBX human protein, clone D18 (SEQ ID NO:35), classified in class 530, subclass 387.1.

XIII. Claims 12-13, drawn to an antagonist to MAFBX protein or pathway, classified in class 514, subclass 12.

XIV. Claims 14-27, drawn to methods of screening compounds that affect MAFBX activity or ubiquination using a host cell expressing MAFBX, classified in class 435, subclass 6.

XV. Claim 28, drawn to methods of detecting muscle atrophy, classified in class 435, subclass 7.8.
XVI. Claim 29, drawn to methods of inhibiting atrophy, classified in class 435, subclass 4.
XVII. Claims 30-32, drawn to methods of treatment using a compound that modules MAFBX, classified in class 514, subclass 12.

3. The inventions are distinct, each from the other because of the following reasons:

Groups I-III are drawn to polynucleotides encoding MAFBX proteins from rat and humans (two clones). Each Group is classified identically. However, these Groups are distinct, each from the other, by virtue of their distinct structures. Each SEQ ID NO has a different structure that is unrelated, except via the name assigned to the encoded protein. No consensus sequence describing the Groups I-III is disclosed or claimed. Moreover, these polynucleotides are only described in the instant specification using their structures; the abbreviation "MAFBX" is assigned no function and is described only by way of expression patterns. Thus, each of these polynucleotides, as defined by their structures, is patentably distinct from the others. Moreover, a search of any two of the Groups would be undue considering the entirely distinct structure search that would not overlap whatsoever, this search cannot easily be augmented by a text search that could include the source species since no function is assigned to the encoded protein. Concerning M.P.E.P. § 803.04 and the restriction of nucleotide sequences, the reasonable number of sequences in the instant application is *no more than one* due to the extensive searching required for nucleotide sequences encoding proteins. Thus, Groups I-III are patentably distinct, each from the other. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II is not required for Group III, restriction for examination purposes as indicated is proper.

Groups IV-VI are distinct, each from the other, Groups VII-IX are distinct, each from the other, and Groups X-XII are distinct, each from the other, for the reasons cited above for the related DNA sequences.

The DNA of Groups I-III are related to the proteins of Groups IV-VI by virtue of the fact that the DNA encode the proteins. The DNA molecule has utility for the recombinant production of the protein in a host cell. Although the DNA and the protein are related, they are distinct inventions because they are wholly different in structure and function. A DNA's structure is comprised of nucleotides while a protein's structure comprised of amino acid; the DNA's function is to encode a protein while a protein's function is variable, and in this case, undefined. Therefore, Groups I-III are patentably distinct from Groups IV-VI. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper. While Groups I-III and Groups IV-VI can be identically classified under U.S. Patent Classification guidelines, to search them together would present a search burden on the Examiner due to the extensive databases of non-patent literature. For example, claims in Group IV, drawn to polypeptides, must be searched not only in commercial amino acid sequence databases, but also in textual databases because isolated polypeptides are often disclosed without the benefit of sequence information although the amino acid sequence is inherently the same as the sequence claimed. Additionally, the nucleic acid sequences must be searched in distinct nucleic acid sequence commercial databases. Thus, Groups I-III and Groups IV-VI have been appropriately restricted on the basis of being both independent or distinct and presenting a search burden on the Examiner if they were to be searched together.

Groups I-III, drawn to nucleic acids, and Groups VII-IX, drawn to transgenic animals, are related because the transgenic animals comprise at least one nucleic acid from Groups I-III. However, nucleic acids and transgenic animals are wholly different compounds having different compositions and functions as evidenced by their distinct class/subclass classifications. Therefore, Groups I-III are patentably distinct from Groups VII-IX. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Groups I-III, drawn to polynucleotides, and Groups X-XII, drawn to antibodies, are related by virtue of the polypeptides that are encoded by the polynucleotides and necessary for the production of the antibody. However, the DNA itself is not necessary for antibody production and both are wholly different compounds having different compositions and functions. Therefore, Groups I-III are patentably distinct from Groups X-XII. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

The DNA of Groups I-III and the antagonist of Group XIII are related because the DNA encodes the protein, which is blocked by the antagonist. However, the DNA and antagonist do not require each other for their practice, are not disclosed as capable of use together, and have different modes of operation and different functions. Therefore, Groups I-III are patentably distinct from Group XIII. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Groups I-III and Group XIV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the products can be used in a materially different process of using that product, such as in the recombinant production of protein. Thus, Groups I-III are patentably distinct from Group XIV. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Groups I-III are related to Groups XV-XVII by virtue of the fact that the DNA encodes the protein, MAFBX, at issue in each of the methods. However, the methods neither use nor produce the DNA. Thus, Groups I-III are patentably distinct from Groups XV-XVII. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Groups IV-VI, drawn to polypeptides, and Groups VII-IX, drawn to transgenic animals, are related because the transgenic animals comprise at least one nucleic acid that encodes the polypeptides. However, polypeptides and transgenic animals are wholly different compounds having different compositions and functions as evidenced by their distinct class/subclass classifications. Therefore, Groups IV-VI are patentably distinct from Groups VII-IX. Because these inventions are distinct for the reasons given above and have acquired a separate status in

the art as shown by their different classification, restriction for examination purposes as indicated is proper.

The proteins of Groups IV-VI and the antibodies of Groups X-XII are related by virtue of being the cognate antigen (protein) necessary for the production of the antibody. Although the protein and antibody are related due to the necessary steric complementarity of the two, they are distinct inventions because they are functionally distinct chemical entities and because the proteins can be used in processes materially distinct from the process to produce antibody, such as in a enzyme activity assays. Furthermore, the proteins can be made using other and materially distinct processes from those used to make an antibody; for example, the proteins can be made using organic synthesis while antibody production can be *in vivo*. Therefore, Groups IV-VI are patentably distinct from Groups X-XII. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Groups IV-VI are related to Group XIII because the proteins of Groups IV-VI are blocked by the antagonists of Group XIII. While antagonists are used to affect the activity of the protein, these compounds may also be useful in affecting other proteins. Additionally, the proteins are useful in the absence of antagonists, such as in enzyme activity assays including substrates alone. Therefore, Groups IV-VI are patentably distinct from Group III. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Groups IV-VI are related to the methods of Groups XIV-XVII by virtue of the proteins being affected or measured in the treatment or detection methods. However, the proteins are neither used nor made in the methods. Thus, Groups IV-VI are patentably distinct from each of Groups XIV-XVII. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

The transgenic animals of Groups VII-IX and the antibodies of Groups X-XII are related by virtue of the polypeptide which is encoded by the nucleic acids comprised in the transgenic animals and which polypeptide is the cognate antigen necessary for the production of the antibodies. However, antibodies and transgenic animals are wholly different compounds having different compositions and functions as evidenced by their distinct class/subclass classifications. Therefore, Groups VII-IX are patentably distinct from Groups X-XII. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

The transgenic animals of Groups VII-IX and the antagonists of Group XIII are related because the DNA of the transgenic animals encodes the protein that is blocked by the antagonist. However, the transgenic animals and the antagonist do not require each other for their practice, are not disclosed as capable of use together, and have different modes of operation and different functions. Therefore, Groups VII-IX are patentably distinct from Group XIII. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

The transgenic animals of Groups VII-IX and the methods of screening compounds of Group XIV are related by virtue of the DNA which is used in the methods and which is introduced into the transgenic animals. While the transgenic animals are useful for studying the *in vivo* affects of the polypeptides, the transgenic animals themselves are not necessary to practice the methods nor are the transgenic animals disclosed as capable of use with said methods. Therefore, the Groups VII-IX are patentably distinct from Group XIV. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Groups VII-IX are related to the methods of Groups XV-XVII by virtue of the proteins, encoded by the DNA of the transgenic animals, being affected or measured in the treatment or detection methods. However, the transgenic animals are neither used nor made in the methods. Thus, Groups VII-IX are patentably distinct from each of Groups XV-XVII. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Groups X-XII are related to the antagonists of Group XIII by virtue of the protein, which is specific for the antibodies of Groups X-XII and which is antagonized by the antagonists. However, the antibodies and the antagonists do not require each other for their practice, are not disclosed as capable of use together, and have different modes of operation and different functions. Therefore, Groups X-XII are patentably distinct from Group XIII. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art

as shown by their different classification, restriction for examination purposes as indicated is proper.

Groups X-XII are related to the methods of Groups XIV, XVI, and XVII by virtue of the proteins, specific for the antibodies, being affected or measured in the treatment or detection methods. However, the antibodies are neither used nor made in the methods. Thus, Groups X-XII are patentably distinct from each of Groups XIV, XVI, and XVII. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Groups X-XII and Group XV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the antibodies can be used for a materially distinct process of using the product, such in detection in fractionation procedures during recombinant protein purification. Thus, Groups X-XII are patentably distinct from Group XV. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Group XIII and Groups XIV, XVI, and XVII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that

product (M.P.E.P. § 806.05(h)). In the instant case, the methods can be practiced with a materially different product, such as using an agonist to modulate MAFBX activity. Thus, Group XIII and Groups XIV, XVI, and XVII are patentably distinct, each from the other. Because these inventions are distinct for the reasons given above and the search required for Group XIII is not required for Groups XIV, XVI, or XVIII, restriction for examination purposes as indicated is proper.

Group XIII is related to the methods of Group XV by virtue of the proteins, specific for the antagonists, being measured in the detection methods. However, the antagonists are neither used nor made in the methods. Thus, Group XIII is patentably distinct from Group XV. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

The methods of Groups XIV-XVII are all related by virtue of their modulation and/or screening of MAFBX. However, each of these methods is distinct from the others by virtue of their distinct methods steps and products. Thus, Groups XIV-XVII are patentably distinct. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Notice of Possible Rejoinder

4. The Examiner notes that if product claims in any of Groups I-III or Groups X-XII or Group XIII are found directed to an allowable product, then process claims in Group XIV or Group XV or Groups XIV, XVI, or XVIII, which are directed to processes of using the

patentable product, previously withdrawn from consideration as a result of a restriction requirement, would now be rejoined pursuant to the procedures set forth in the Official Gazette notice dated March 26, 1996 (1184 O.G. 86; see also M.P.E.P. § 821.04, *In re* Ochiai, and *In re* Brouwer). Since process claims would be rejoined and fully examined for patentability under 37 C.F.R. § 1.104, Applicants are instructed to amend said claims as deemed necessary according to rejections made against the elected claims.

Election

5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. § 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(i).

Conclusion

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (703) 305-1229. The examiner can normally be reached on Monday through Friday, from 9:00am to 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (703) 308-3804. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Kathleen M Kerr
Examiner
Art Unit 1652

January 14, 2004